

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1448A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Application Number		10/009,520			
Filing Date		May 3, 2002			
First Named Inventor		MITRANI Eduardo N.			
Art Unit		1635 / 632			
Examiner Name		Wili-Cheng Winston Shen			
Attorney Docket Number		01/22858			
Sheet				of	

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
W.S.	1	US-3,984,533	05-5-1976	Uzgis	
W.S.	2	US-3,996,345	07-7-1976	Ullman et al.	
W.S.	3	US-3,867,517	02-18-1975	Ling	
W.S.	4	US-3,850,578	11-26-1974	McConnell et al.	
W.S.	5	US-2003/0157074	08-21-2003	Mitrani	
W.S.	6	US-2003/0152561	08-14-2003	Mitrani	
W.S.	7	US-2003/0152909	08-14-2003	Mitrani	
W.S.	8	US-2003/0152562	08-14-2003	Mitrani	
W.S.	9	US-6,001,647	12-14-1999	Peek et al.	
W.S.	10	US-6,303,136	10-16-2001	Li et al.	
W.S.	11	US-5,871,767	02-16-1999	Dionne et al.	
W.S.	12	US-5,861,313	01-19-1999	Pang et al.	
W.S.	13	US-3,734,851	05-22-1973	Matsumura	
W.S.	14	US-5,032,508	07-16-1991	Naughton et al.	
W.S.	15	US-4,835,102	05-30-1989	Bell et al.	
W.S.	16	US-4,888,291	12-19-1989	Barrandon et al.	
W.S.	17	US-4,798,885	01-17-1989	Mason et al.	
W.S.	18	US-5,387,576	07-7-1995	Mitrani	
W.S.	19	US-2002/0039786	04-4-2002	Reid et al.	
W.S.	20	US-4,369,788	01-25-1983	Goald	
W.S.	21	US-4,043,343	08-23-1977	Williams	
W.S.	22	US-6,030,833	02-29-2000	Seebach et al.	
W.S.	23	US-2002/0012661	01-31-2002	Saito et al.	
W.S.	24	US-5,670,148	09-23-1997	Sherwin et al.	
W.S.	25	US-5,885,971	03-23-1999	German et al.	
W.S.	26	US-4,533,635	06-6-1985	Guédon born Saglier et al.	
W.S.	27	US-4,940,666	07-10-1990	Boyce et al.	
W.S.	28	US-5,282,859	01-1-1994	Eisenberg	
W.S.	29	US-5,292,655	08-8-1994	Wille Jr.	
W.S.	30	US-4,353,888	10-12-1982	Sefton	
W.S.	31	US-4,391,909	05-5-1983	Lim	
W.S.	32	US-4,666,828	05-19-1987	Gusella	
W.S.	33	US-4,683,202	07-28-1987	Mullis	
W.S.	34	US-4,736,866	04-12-1988	Leder et al.	
W.S.	35	US-4,801,531	01-31-1989	Frossard	
W.S.	36	US-4,879,219	07-7-1989	Wands et al.	
W.S.	37	US-4,892,538	09-9-1990	Aebischer	
W.S.	38	US-5,106,627	04-21-1992	Aebischer	
W.S.	39	US-5,175,383	12-29-1992	Leder et al.	
W.S.	40	US-5,175,384	12-29-1992	Krimpenfort et al.	
W.S.	41	US-5,175,385	12-29-1992	Wagner et al.	
W.S.	42	US-5,192,659	09-9-1993	Simons	
W.S.	43	US-5,221,778	06-22-1993	Byrne et al.	
W.S.	44	US-5,272,057	12-21-1993	Smulson et al.	

W.S.	45	US-5,288,846	02-22-1994	Quertermous et al.	
W.S.	46	US-5,298,422	03-29-1994	Schwartz et al.	
W.S.	47	US-5,347,075	09-13-1994	Sorge	
W.S.	48	US-5,360,735	01-1-1994	Weinshank et al.	
W.S.	49	US-5,387,742	07-7-1995	Cordell	
W.S.	50	US-5,464,764	07-7-1995	Capecchi et al.	
W.S.	51	US-5,487,992	01-30-1996	Capecchi et al.	
W.S.	52	US-6,472,200	10-29-2002	Mitrani	
W.S.	53	US-4,883,666	11-28-1989	Sabel et al.	
W.S.	54	US-3,791,932	02-12-1974	Schuurs et al.	
W.S.	55	US-3,839,153	01-1-1974	Schuurs et al.	
W.S.	56	US-3,853,987	12-10-1974	Dreyer	
W.S.	57	US-3,935,074	01-27-1976	Rubinstein et al.	
W.S.	58	US-4,034,074	05-5-1977	Miles	
W.S.	59	US-4,098,876	04-4-1978	Piaso et al.	
W.S.	60	US-5,011,771	04-30-1991	Bellet et al.	
W.S.	61	US-5,281,521	01-25-1994	Trojanowski et al.	
W.S.	62	US-3,850,752	11-26-1974	Schuurs et al.	
W.S.	63	US-3,901,654	08-26-1975	Gross	
W.S.	64	US-6,372,482	04-16-2002	Mitrani	

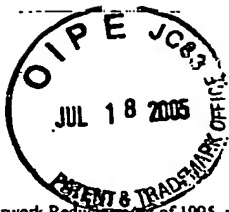
#### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Documents	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6
		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
W.S.	65	PCT WO 99/49807	07-7-1999	Mitrani		
W.S.	66	PCT WO 96/15225	05-23-1996	Mitrani		
W.S.	67	PCT WO 03/040686	05-15-2003	Pearlman et al.		
W.S.	68	PCT WO 03/049783	06-19-2003	Bellomo et al.		
W.S.	69	PCT WO 03/039382	05-15-2003	Pearlman et al.		
W.S.	70	PCT WO 03/049626	06-19-2003	Bellomo et al.		
W.S.	71	PCT WO 98/39035	09-11-1998	Herlyn et al.		
W.S.	72	PCT WO 91/12334	08-22-1991	Warren et al.		
W.S.	73	EP 0364306	04-18-1990	Chao		
W.S.	74	EP 0418035	03-3-1995	Kemp et al.		
W.S.	75	EP 0361957	04-4-1990	Bell et al.		
W.S.	76	EP 0271211	08-19-1992	Twardzik et al.		
W.S.	77	EP 0222491	05-20-1987	Mason et al.		
W.S.	79	PCT WO 01/00859	04-4-2001	Mitrani		
W.S.	80	PCT WO 97/27742	07-7-1997	Paik		
W.S.	81	PCT WO 96/30492	03-3-1996	Hu et al.		
W.S.	82	PCT WO 93/14200	07-22-1993	Wadworth et al.		
W.S.	83	PCT WO 94/06908	03-31-1994	Littman et al.		
W.S.	84	PCT WO 94/23049	10-13-1994	Gearhart et al.		
W.S.	85	PCT WO 94/28123	08-8-1994	Thompson et al.		
Examiner Signature		/Wu Cheng Winston Shen/ (08/30/2006)		Date Considered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.87 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

\* Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1448A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/009,520
		Filing Date	May 3, 2002
		First Named Inventor	MITRANI Eduardo N.
		Group Art Unit	4635/632
		Examiner Name	Wu-Cheng Wang Shen
		Attorney Docket Number	01/22858
Sheet	Of	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W.S.	86	Iruela-Arispe et al. "Angiogenesis: A Dynamic Balance of Stimulators and Inhibitors", (1997) Thrombosis and Haemostasis 78(1), 672-677	
W.S.	87	Mansbridge et al. "Three-Dimensional Fibroblast Culture Implant for the Treatment of Diabetic Foot Ulcers: Metabolic Activity and Therapeutic Range", Tissue Engineering, 4(4): 403-414, 1998.	
W.S.	88	Freshney "Culture of Animal Cells, A Manual of Basic Technique": 297-307, 1987. Esp. P.302.	
W.S.	89	Kondo et al. "Long-Term Organ Culture of Rabbit Skin: Effect of EGF on Epidermal Strucuter In Vitro", Journal of Investigative Dermatology, 95(4): 397-402, 1990. P.397, Col.2.	
W.S.	90	Agren et al. "Human Fetal Pancreas: Culture and Function In Vitro", Diabetes, 29(Suppl.1): 64, 1980.	
W.S.	91	Choi et al. "TGF-Beta and Retinoic Acid: Regulators of Growth and Modifiers of Differentiation in Human Epidermal Cells", Cell Regulation, 1: 791-809, 1990.	
W.S.	92	Rheinwald "Serial Cultivation of Normal Human Epidermal Keratinocytes", Methods in Cell Biology, 21A: 229-254, 1980.	
W.S.	93	Pinkus "Examination of the Epidermis by the Strip Method of Removing Horny Layers", J. of Invest. Derm.: 383-386, 1951.	
W.S.	94	Soyer et al. "Extracorporeal Assist of Anhepatic Animals with Liver Slice Perfusion", The American Journal of Surgery, 1973.	
W.S.	95	Eiseman et al. "Prosthetics in Hepatic Assistance", Transplantation Proceedings, 3(4): 1519, 1971.	
W.S.	96	Gerlach "Hepatocyte Culture and Bioreactor Design for Liver Support Systems", in: 'Acute Liver Failure', Cambridge University Press, Chap.19, 1997.	
W.S.	97	Levine "The Growth of Adult Human Skin In Vitro", Br. J. Derm., 86: 481, 1972.	
W.S.	98	Boyce et al. "Calcium-Regulated Differentiation of Normal Human Epidermal Keratinocytes in Chemically Defined Clonal Culture and Serum-Free Serial Culture", Journ. of Investigative Dermatology, 81: 33s-40s, 1983.	
W.S.	99	Boisseau et al. "Production of Epidermal Sheets in a Serum Free Culture System: A Further Appraisal of the Role of Extracellular Calcium", Journal of Dermatological Science, 3: 111-120, 1992.	
W.S.	100	Granov et al. "Extracorporeal Fixation of Liver Slices Onto the System of 'Artificial Kidney' Apparatus", Pub Med., 116(3): 106-109, 1976.	
W.S.	101	Watson et al. "Sheep Vibrissa Dermal Papillae Induce Hair Follicle Formation in Heterotypic Skin Equivalents", British Journal of Dermatology, 131: 827-835, 1994.	
W.S.	102	Varani et al. "All-Trans Retinoic Acid and Extracellular Ca <sup>2+</sup> Differentially Influence Extracellular Matrix Production by Human Skin in Organ Culture", American Journal of Pathology, 142(6): 1813-1822, 1993.	
W.S.	103	Reynolds et al. "Cultured Dermal Papilla Cells Induce Follicle Formation and Hair Growth by Transdifferentiation of an Adult Epidermis", Development, 115: 587-593, 1992.	
W.S.	104	Gurdon "The Generation of Diversity and Pattern in Animal Development", Cell, 68: 185-199, 1992.	
W.S.	105	Sugihara et al. "Reconstruction of the Skin in Three-Dimensional Collagen Gel Matrix Culture", In Vitro Cell Dev. Biol., 27A: 142-146, 1991.	
W.S.	106	Li et al. "Skin Toxicity Determined In Vitro by Three-Dimensional, Native-State	

		Histoculture", Proc. Natl. Acad. Sci., 88: 1908-1912, 1991.	
W.S.	107	Parenteau et al. "Epidermis Generated In Vitro: Practical Considerations and Applications", Journal of Cellular Biochemistry, 45: 245-251, 1991.	
W.S.	108	Norris "A Generous Contribution by Roche Dermatology Division of Hoffman-La Roche Inc. to the Endowment for the Journal has Supported this Issue", The Journal of Investigative Dermatology, 95(4), 1990.	
W.S.	109	Goldberg Alternative Methods in Toxicology Series, Vol.7, 1989. Preface.	
W.S.	110	Bell et al. "Testskin: A Hybrid Organism Covered by A Living Human Skin Equivalent Designed for Toxicity and Other Testing", Alternative Methods in Toxicology, 6(Chap.A3): 15, 1988.	
W.S.	111	Kao et al. "Skin Penetration and Metabolism of Topically Applied Chemicals in Six Mammalian Species, Including Man: An In Vitro Study With Benzo[a]pyrene and Testosterone", Toxicology and Applied Pharmacology, 81: 502-516, 1985.	
W.S.	112	Coulomb et al. "Interactions Dermo-Epidemiques et Pharmacologie Cutanee", Pathologie Biologie, 40(2): 139-146, 1992.	
W.S.	113	Parrish et al. "Precision-Cut Tissue Slices: Applications in Pharmacology and Toxicology", Life Sciences, 57(21): 1887-1901, 1995.	
W.S.	114	Burke et al. "Preparation of Clone Libraries in Yeast Artificial-Chromosome Vectors", in Methods in Enzymology, 194:251-270, 1991	
W.S.	115	Carey et al. "An Amino-Terminal Fragment of GAL4 Binds DNA as a Dimer", Academic Press Ltd. (1989), J. Mol. Biol., 209:423-4332;	
W.S.	116	Gale et al. "Growth Factors Acting via Endothelial Cell-Specific Receptor Tyrosine Kinases: VEGF's, Angiopoietins, and Ephrins in Vascular Development", Genes and Development 13, 1055-1066 (1999)	
W.S.	117	Huxley et al. "The Human HPRT Gene on a Yeast Artificial Chromosomes is Functional when Trasferred to Mouse Cells by Cell Fusion", Genomics, 9:742-750 (1991)	
W.S.	118	Lamb et al. "Introduction and Expression of the 400 Kilobase Precursor Amyloid Protein Gene in Transgenic Mice", Nature Genetics, 5:22-29, 1993	
W.S.	119	Pearson et al. "Expression of the Human Beta-Amyloid Precursor Protein Gene From a Yeast Artificial Chromosome in Transgenic Mice.", Proc. Natl. Acad. Sci. USA, 1993, 90:10578-82	
W.S.	120	Cress et al. "Critical Structural Elements of the VP16 Transcriptional Activation Domain", (1991) Science, 251:87-90;	
W.S.	121	Davies et al. "Targeted Alterations in Yeast Artificial Chromosomes for Inter-Species Gene Transfer", Nucleic Acids Research, 20 (11) 2693-2698, 1992;	
W.S.	122	Dickinson et al. "High Frequency Gene Targeting Using Insertional Vectors", Human Molecular Genetics, 2(8):1299-1302, 1993	
W.S.	123	Futterer et al. "Translation of a Polycistronic mRNA in the Presence of the Cauliflower Mosaic Virus Transactivator Protein", (1991) EMBO J. 10:3887-3896;	
W.S.	124	Jakobovits et al. "Germ-Line Transmission and Expression of a Human-Derived Yeast Artificial Chromosome", Nature, 362:255-261 (1993).	
W.S.	125	Rothstein "Targeting, Disruption, Replacement, and Allele Rescue: Integrative DNA Transformation in Yeast", Methods in Enzymology", 194:281 - 301 (1991);	
W.S.	126	Sadowski et al. "GAL4-VP16 is an Unusually Potent Transcriptional Activator", (1988), Nature, 335:563-564	
W.S.	127	Schedl et al. "A Yeast Artificial Chromosome covering The Tyrosinase Gene Confers Copy Number-Dependent Expression in Transgenic Mice", Nature, 362:258-261, (1993)	
W.S.	128	Capecchi "Altering the Genome by Homologous Recombination", Science, 244:1288-1292, 1989	

Signature	/Wu Cheng Winston Shen/ (08/30/2006)	Considered	
-----------	--------------------------------------	------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.  
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.**

**SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/009,520
				Filing Date	May 3, 2002
				First Named Inventor	Eduardo N. MITRANI
				Group Art Unit	1635/632
Examiner Name	ANGELL JONE WIS-Cheng Winston Shen				
Sheet	2	of	3	Attorney Docket Number	01/22858
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
W.S.	14	Soyer et al. "Extracorporeal Assist of Anhepatic Animals With Liver Slice Perfusion", The American Journal of Surgery, P.21-26, 1973.			
W.S.	15	Rubanyi "The Future of Human Gene Therapy", Molecular Aspects of Medicine, 22(3): 113-142, 2001.			
W.S.	16	Parrish et al. "Minireview : Precision-Cut Tissue Slices: Applications in Pharmacology and Toxicology", Life Sciences, 57(21): 1887-1901, 1995.			
W.S.	17	Villeval et al. "Retrovirus-Mediated Transfer of the Erythropoietin Gene in Hematopoietic Cells Improves the Erythrocyte Phenotype in Murine $\beta$ -Thalassemia", Blood, 84(3): 928-933, 1994.			
W.S.	18	Descamps et al. "Organoids Direct Systematic Expression of Erythropoietin in Mice", Gene Therapy, 2: 411-417, 1995.			
W.S.	19	Palù et al. "In Pursuit of New Developments for Gene Therapy of Human Diseases", J. Biotechnology, 68: 1-13, 1999.			
W.S.	20	Romano et al. "Gene Transfer Technology in Therapy: Current Applications and Future Goals", Stem Cell, 17: 191-202, 1999.			
W.S.	21	Kappel et al. "Regulating Gene Expression in Transgenic Animals", Current Opinion in Biology, 3: 548-553, 1992.			
W.S.	22	Mullins et al. "Transgenesis in Nonmurine Species", Hypertension, 22(4): 630-633, 1993.			
W.S.	23	Mullins et al. "Transgenesis in the Rat and Larger Mammals", J. Clin. Invest., 97(7): 1557-1560, 1996.			
W.S.	24	Houdebine "Production of Pharmaceutical Proteins From Transgenic Animals", J. Biotechnology, 34: 269-287, 1994.			
W.S.	25	Wall "Transgenic Livestock: Progress and Prospects for the Future", Transgenology, 45: 57-68, 1996.			
W.S.	26	Sigmund "Viewpoint: Are Studies in Genetically Altered Mice Out of Control?", Arterioscler. Thromb. Vasc. Biol., 20: 1425-1429, 2000.			
W.S.	27	Niemann "Transgenic Farm Animals Get Off the Ground", Transgenic Research, 7: 73-75, 1998.			
W.S.	28	Crystal "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", Science, 270: 404-410, 1995.			
W.S.	29	Verma et al. "Gene Therapy - Promises, Problems and Prospects", Nature, 389: 239-242, 1997.			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/009,520
				Filing Date	May 3, 2002
				First Named Inventor	Eduardo N. MITRANI
				Group Art Unit	1635/62
				Examiner Name	ANGEL JON E
Sheet	3	of	3	Attorney Docket Number	01/22858
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
W.S.	30	Deonarin "Ligand-Targeted Receptor-Mediated Vectors for Gene Delivery", Exp. Opin. Ther. Patents, 8(1): 53-69, 1998.			
W.S.	31	Miller et al. "Targeted Vectors for Gene Therapy", FASEB J., 9: 190-199, 1995.			
W.S.	32	Eck et al. "Gene-Based Therapy", in: Goodman & Gilman's 'The Pharmacological Basis of Therapeutics', 9/E, Chap.5: 77-101, 1997.			
W.S.	33	Ledley "Pharmaceutical Approach to Somatic Gene Therapy", Pharm. Res., 13(11): 1595-1614, 1996.			
W.S.	34	Saadi et al. "Immunology of Xenotransplantation", Life Sciences, 62(5): 365-387, 1998.			
W.S.	35	Inverardi et al. "Cell Transplantation", in: 'Transplantation Biology: Cellular and Molecular Aspects', Raven Pub., Chap. 56, 1996.			
W.S.	36	Philpott et al. "Rat Hair Follicle Growth In Vivo", Br. J. Derm., 127: 600-607, 1992.			
W.S.	37	Lingna "Skin Toxicity Determined In Vitro by Three-Dimensional, Native-State Histoculture", Proc. Natl. Acad. Sci. USA, 88: 1908-1912, 1991.			
W.S.	38	Cameron "Recent Advances in Transgenic Technology", Molecular Biotechnology, 7: 253-265, 1997.			
W.S.	39	Eto et al. "Purification and Characterization of Erythroid Differentiation Factor (EDF) Isolated From Human Leukemia Cell Line THP-1", Biochemical and Biophysical Research Communications, 142(3): 1095-1103, 1987.			
W.S.	40	Chesnokova et al. "The Thymic Factor Tactivin Prevents ACTH From Stimulating Steroidogenesis by Mouse Adrenal Cells", Institute of Cytology and Genetics, USSR Academy of Science, 1990.			
Signature		/Wu Cheng Winston Shen/ (08/30/2006)			Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.87 and 1.88. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.

**DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



A circular stamp from the Intellectual Property Office (IPO). The text "O I P E" is at the top, "JC139" is at the top right, "DEC 16 2003" is in the center, and "PATENT &amp; TRADEMARK OFFICE" is at the bottom.

Approved for use through 10/31/99 OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**Complete if Known**

*(use as many sheets as necessary)*

Application Number	10/009,520
--------------------	------------

Filing Date	12/11/2001
-------------	------------

First Named Inventor	Mitrani
----------------------	---------

Group Art Unit	1622
----------------	------

Examiner Name	W. Cheng Winston Shen
Attorney Docket Number	01/22858

Attorney Docket Number	01/22858
------------------------	----------

Sheet

**2**

Of

2

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

**Examiner  
Initials**

Cite  
No.<sup>1</sup>

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

 $\tau^2$ 

W.S.

Achim et al, "In vivo Model of HIV Infection of the Human Brain", *Advances in Neuroimmunology*, 4:261-264, 1994

W.S.

Sampson et al, "Colonization of Human Lung Grafts in SCID-hu Mice by Human Colon Carcinoma Cells", *Int. J. Cancer*, 65:864-869, 1996

W.S.

Epstein et al, "Human Neural Xenografts: Progress In Developing An *In-Vivo* Model To Study Human Immunodeficiency Virus (HIV) And Human Cytomegalovirus (HCMV) Infection" *Adv Neuroimmunol.*, 4(3):257-60, 1994

**Examiner  
Signature**

/Wu Cheng Winston Shen/ (08/29/2006)

Date \_\_\_\_\_

**Considered**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Unique citation designation number. <sup>2</sup>. Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231.

**DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

11

Approved for use through 10/31/2002. OMB 0851-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

**Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.**

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/009,250
				Filing Date	December 5, 2001
				First Named Inventor	Mario MOLINARI
				Group Art Unit	1672
				Examiner Name	Wu-Cheng Winston Shen
Sheet	1	of	2	Attorney Docket Number	P/61813

[illegible][illegible]

Examiner Signature	/Wu Cheng Winston Shen/ (08/29/2006)	Date Considered	
-----------------------	--------------------------------------	--------------------	--

\*EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	10/009,250	
			Filing Date	December 5, 2001	
			First Named Inventor	Mario MOLINARI	
			Group Art Unit	1632	
			Examiner Name	Wu-Cheng Winston Shen	
Sheet	2	of	2	Attorney Docket Number	P/61813

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W. S.		Tmn Architecture for SDH Networks Using Is-is Routing Protocol: Design and Performances, PROCEEDINGS OF INTERNATIONAL CONFERENCE ON COMMUNICATION TECHNOLOGY, Vol. 1, 5-7 May 1996, pp. 223-227, L. Ambrosol, et al.	
W. S.		SDH Management Network: Architecture, Routing and Addressing, PROCEEDINGS OF THE GLOBAL TELECOMMUNICATIONS CONFERENCE (GOLBECOM), U.S. New York, IEEE, Vol. November 29, 1993, pp. 223-228, H. Katz, et al.	
W. S.		An Approach for Cluster-Based Multicast Routing In Large-Scale Networks, IEICE TRANSACTIONS ON COMMUNICATIONS, JP, Institute of Electronics Information and Comm. Eng. Tokyo, Vol. E81-B, No. 5, May 1, 1998, pp. 1029-1040.	

Examiner Signature	/Wu Cheng Winston Shen/ (08/29/2006)	Date Considered	
--------------------	--------------------------------------	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.